



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Aesculap Implant Systems, LLC
Ms. Lisa M. Boyle
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

May 29, 2015

Re: K150544

Trade/Device Name: Columbus Total Knee System, Columbus Revision Knee System,
EnduRo Knee System

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained
cemented prosthesis

Regulatory Class: Class II

Product Code: JWH

Dated: May 4, 2015

Received: May 5, 2015

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K150544

Device Name

Columbus Total Knee System, Columbus Revision Knee System, EnduRo Knee System

Indications for Use (Describe)

Columbus Total Knee System, Columbus Revision Knee and EnduRo Knee System are indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

Hinge Knee Systems are designed for use in patients in primary or revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments are absent or insufficient. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.

The Columbus Total Knee System, Columbus Revision Knee System and EnduRo Knee System are designed for use with bone cement.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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B. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

**Columbus Total Knee System
Columbus Revision Knee System
EnduRo Knee System**

February 24, 2015

COMPANY: Aesculap® Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034

**ESTABLISHMENT
REGISTRATION NUMBER:** 3005673311

CONTACT: Lisa M. Boyle
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DEVICE

TRADE NAMES: Columbus Total Knee System
Columbus Revision Knee System
EnduRo Knee System

COMMON NAME: Total Knee System

DEVICE CLASS: CLASS II

PRODUCT CODE: JWH

REGULATION NUMBER: 888.3560

CLASSIFICATION NAME: Knee Joint Patellofemorotibial Polymer/Metal/Polymer
Semi constrained Cemented Prosthesis

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes allowing the use of the previously cleared VEGA patella (K101281) with Aesculap's Columbus Total Knee System, Columbus Revision Knee System and EnduRo Knee System is a line extension that remains substantially equivalent to the currently marketed subject knee systems. There have been no changes to any of the subject components.

DEVICE DESCRIPTION

The VEGA patella is manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) that incorporates a wrought stainless steel radiographic marker. The VEGA patella is intended to articulate with the femoral and tibial components of the Columbus Total Knee System, Columbus Revision Knee System or EnduRo Knee System.

The VEGA patella is sterile and intended for single use only.

INDICATIONS FOR USE

Columbus Total Knee System, Columbus Revision Knee and EnduRo Knee System are indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Posterior Stabilized (PS) components are also for absent or non-functioning posterior cruciate ligament and severe anteroposterior instability of the knee joint.

Hinge Knee Systems are designed for use in patients in primary or revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments are absent or insufficient. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.

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TECHNOLOGICAL CHARACTERISTICS (Compared to the Predicate)

The VEGA patella is a legally marketed component of Aesculap VEGA Knee System that was originally cleared via 510(k) K101281. The introduction of the VEGA patella to the subject knee systems does not impact the fundamental scientific technology of Columbus Total Knee System (K120955), Columbus Revision Knee System (K122985), and EnduRo Knee System (K120955).

PERFORMANCE DATA

As a result of the risk analysis, a geometrical comparison and an evaluation of lateral stability were used to determine cross compatibility of Aesculap VEGA patella with Aesculap's Columbus, Columbus Revision and EnduRo Knee Systems. Results of the geometrical analysis and lateral stability demonstrated substantial equivalence and showed that there are no new risks associated with the alternate use of the VEGA patella in the subject Columbus Total Knee System (K120955), Columbus Revision Knee System (K122985), and EnduRo Knee System (K120955).